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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,194

03/25/2004

Michael V. Lipoma

2G02.1-111

6001

23506

7590

01/22/2008

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EXAMINER

OU, JING RUI

ART UNIT

PAPER NUMBER

4123

MAIL DATE

DELIVERY MODE

01/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,194	Applicant(s) LIPOMA ET AL.	
	Examiner JING OU	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,10-12,16-19,21 and 26-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,8,11,12,16,17 and 26-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/12/2004, 12/14/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the non-provisional application filed on March 25, 2004 and the election/restriction requirement response filed on December 12, 2007. Claims 1-2, 5-8, 10-12, 16-19, 21, and 26-36 are pending. Claims 1, 11, and 26 are independent.

Election/Restrictions

2. Applicant's election without traverse of the invention of Group I, Species E, Claims, 1-2, 5-6, 8, 11-12, and 16-17 and addition of new Claims 26-36, in the reply filed on 12/12/2007 is acknowledged.

Information Disclosure Statement

3. The information disclosure statement filed 07/12/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the drive surfaces of the stimulator member and the lancet must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 5-6, 8, 11-12, 16-17, 26-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Verdonk et al (US Pat. No.: 6,306,152).

In regard to Claim 1, Verdonk et al discloses a method of reducing perceived pain resulting from puncturing of skin at a puncture site, said method comprising: generating a sensory distraction at or adjacent the puncture site (Col. 2. lines 59-66);

and puncturing the skin at the puncture site simultaneously with or after the generation of the sensory distraction (Col. 2, lines 59-66).

In regard to Claim 2, the step of generating a sensory distraction and the step of puncturing the skin are performed using a single device (lancet device, 150, Fig. 5 and Col. 2, lines 33-36 and 63-66).

In regard to Claim 5, the step of generating a sensory distraction comprises impacting the puncture site with a stimulator member (skin stabilizer, 152, Fig. 5 and Col. 2, lines 59-66).

In regard to Claim 6, the step of impacting the puncture site with a stimulator member comprises implementing a varied length scheme for timing the puncturing simultaneously with or after the stimulator impact (Col. 6, lines 36-44 and Col. 2, lines 59-66).

In regard to Claim 8, the sensory distraction comprises an impact (Col. 2, lines 59-66).

In regard to Claims 11-12 and 16, Verdonk et al discloses a device for penetrating the skin of a human or animal subject, comprising: a stimulator member (skin stabilizer, 152, Fig. 5) for puncturing the skin at a puncture site; and a lancet (lancet, 104, Fig. 5) for generating a sensory distraction at or adjacent the puncture site before or simultaneously with the puncturing of the skin.

In regard to Claim 17, the means for puncturing the skin further comprises a single drive spring (spring, 168, Fig. 5) for driving both the simulator member and the lancet (col. 6, lines 58-67 and col. 7, lines 1-13).

In regard to Claims 26-27, Verdonk et al discloses a lancing device for penetrating skin, comprising: a housing (164, Fig. 5); a lancet (104, Fig. 5) having a puncturing tip (sharp tip, 138, Fig. 5), wherein the lancet travels along a lancing travel path toward an extended position with the lancet tip extending out of the housing to puncture the skin at a puncture site (Fig. 5 and Col. 6, lines 25-51); and an elongated stimulator member (skin stabilizer, 152, Fig. 5) having an impacting portion (the bottom surface of the skin stabilizer, Fig. 5), wherein the elongated stimulator member travels along a stimulating travel path toward an extended position with the stimulating portion extending out of the housing to impact the skin at or adjacent the puncture site to create a sensory distraction at or adjacent the puncture site before or simultaneously with the puncturing of the skin (Fig. 5 and Col. 6, lines 52-67 and Col. 7, lines 1-18).

In regard to Claim 28, the stimulator member impacting portion is defined by a blunt tip (the bottom tip or end of the skin stabilizer is blunt, Fig. 5).

In regard to Claim 29, a stimulator return spring (spring, 168, Fig. 5) that retracts the stimulator member impacting portion from the extended position back into the housing, and a lancet return spring (spring, 168, Fig. 5) that retracts the lancet tip from the extended position back into the housing (it is inherent that the spring 168 retracts both the stimulator member and the lancet tip from the extended position back into the housing. Therefore, spring 168 is both a stimulator return spring and a lancet return spring).

In regard to Claim 30, the stimulator member and the lancet are arranged in a side-by-side arrangement (Fig. 5).

In regard to Claim 31, the device further comprises a single drive spring (168, Fig. 5) for driving both the simulator member and the lancet(col. 6, lines 58-67 and col. 7, lines 1-13).

In regard to Claim 32, the device further comprises a single drive member (base plate, 162, Fig. 5) that is driven by the single drive spring and that in turn drives the stimulator and the lancet (Col. 6, lines 25-67 and col. 7, lines 1-13).

In regard to Claim 33, the stimulator member has a drive surface (the top surface of the skin stabilizer that contacts the bottom surface of the base plate, Fig. 5) and the lancet has a drive surface (the top surface of the lancet- that contacts the bottom surface of the base plate, Fig. 5), and wherein the drive member has a contact surface that engages the drive surfaces of the stimulator member and the lancet to drive forward both the stimulator member and the lancet (Fig. 5).

In regard to Claim 34, the stimulator drive surface and the lancet drive surface are generally laterally aligned (Fig. 5), and wherein the drive member contact surface is generally flat (Fig. 5).

In regard to Claims 35-36, the stimulator is longer than the lancet (Fig. 5).

Claim Rejections - 35 USC § 103

7. Claim 29, *in the alternative*, is rejected under 35 U.S.C. 103(a) as being unpatentable over Verdonk et al (US Pat. No.: 6,306,152) in view of Burns (US Pat. No.: 4,527,561).

Verdonk et al discloses the device further comprises a stimulator return spring (168, Fig. 5) that retracts the stimulator member impacting portion from the extending

position back into the housing as taught above but fails to disclose a lancet return spring that retracts the lancet tip from the extended position back into the housing.

However, Burns explicitly teaches a lancet return spring (28, Fig. 8) that retracts the lancet tip from the extended position back into the housing (Col. 2, lines 33-36).

Verdonk et al and Burns are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Verdonk et al and Burns before him or her, to modify the lancing device of Verdonk et al to include a lancet return spring as taught by Burns.

The suggestion/motivation for doing so would have been to automatically retract the lancet back into the housing (Burns, Col. 2, lines 29-36) and to maintain the lancet in position (Burns, Col. 4, lines 50-51).

Therefore, it would have been obvious to combine Burns with Verdonk et al to obtain the invention as specified in the instant claim.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Czernecki et al (US Pat. No.: 5,356,420)

Tezuka et al (US Pat. No.: 5,569,287)

Marshall et al (US Pat. No.: 5,611,809)

Freeman et al (US Pat. No.: 5,938,679)

Mauze et al (US Pat. No.: 6,139,562)

Mauzu et al (US Pat. No.: 6,171,325)

Mauze et al (US Pat. No.: 6,176,865)

Lum et al (US Pat. No.: 6,231,531)

Wyszogrodzki (US Pat. No.: 6,248,120)

Rutynowski et al (US Pat. No.: 6,613,064)

Lum et al (US Pat. No.: 6,660,018)

Davison et al (US Pub. No.: 2004/0098010)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036.

The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571)272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRO

/Essama Omgba/
Primary Examiner, Art Unit 3726